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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,572	FADEM, KALFORD C.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2010 has been entered.

2. Claims 1, 23, 28, and 31-32 are amended. Claim 26 is cancelled. Claim 33 is new. **Claims 1-25 and 27-33** remain pending and under prosecution.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "amplifier co-located with the reference and signal electrodes" of **Claim 1** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1-22** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding **Claim 1**, it appears from applicant's arguments that the claims wish to recite a specific configuration of the amplifier being co-located with the reference and signal electrodes. However, it does not appear that any support exists within applicant's disclosure for any particular configuration of the amplifier relative to the electrodes. Also see Drawing Objections above, which appear to lack a showing of both the amplifier itself and its position relative to the electrodes.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claims 1-3, 7, 11, and 13-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al (US Pat No. 5954667) in view of John et al (US Pub No. 20010049480).

8. In regards to **Claim 1**, Finkenzeller et al disclose a screening device, comprising:

a frame 10 shaped to be engageable to a head between a reference location, at least one ear, and a signal detection location, best seen in Figure 1-2;

a reference active electrode 22 attached to the frame at the reference location, wherein the reference active electrode includes a local amplifier 40 co-located with the reference active electrode such that the local amplifier co-located with the reference active electrode is also attached relative to the frame, wherein the local amplifier co-located with the reference active electrode is operable to amplify signals sensed by the reference active electrode, best seen in Figure 1-2;

a signal active electrode 21 attached to the frame at the signal detection location, wherein the signal active electrode includes a local amplifier 40 co-located with the signal active electrode such that the local amplifier co-located with the signal active electrode is also attached relative to the frame, wherein the local amplifier co-located with the signal active electrode is operable to amplify signals sensed by the signal active electrode, best seen in Figure 1-2;

an auditory signal producer 30 positionable by the frame over the ear; and

an auditory evoked response (AER) data processor 1 operably configured to initiate an auditory signal from the auditory signal producer and to perform a signal processing operation on an AER signal sensed across the reference and signal electrodes and amplified by the local amplifier co-located with the reference active electrode and the local amplifier co-located with the signal active electrode, best seen in Figure 1-2 (Col.3: 55-65).

9. However, Finkenzeller et al do not disclose the amplifier as an integral part of the reference active electrode or the signal active electrode. It is noted that since the amplifier 40 is connected to both the reference active electrode and the signal active electrode, it would be obvious to have one amplifier for each or one that amplifiers the signals of both as taught by Finkenzeller et al. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the amplifier as an integral part of the reference active electrode or the signal active electrode, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893), to advantageously produce a more integral device.

10. However, Finkenzeller et al do not disclose a diagnostic analyzer operably configured to characterize the amplified AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a diagnostic analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein

the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a diagnostic analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, as taught by John et al, to effectively determine the presence of a neurological condition.

11. **Claim 2**: Finkenzeller et al disclose a cantilevered flexible arm 12 connecting the signal electrode 21 to the frame 10, best seen in Figure 1.

12. **Claim 3**: Finkenzeller et al disclose a second signal electrode 21 attached to the frame, best seen in Figure 2.

13. In regards to **Claim 7**, Finkenzeller et al in combination with John et al disclose the invention above as claimed including teaching that the complete device may be mounted on the frame (Col.4: 65-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a flexible printed circuit harness containing the electrodes and communication paths to the AER data processor which is well known to one skilled in the art as an effective circuit and electrode structure to effectively have all components of the device mounted onto the frame and shaped for conforming to the head under the resilient urging of the frame.

14. **Claim 11**: Finkenzeller et al in combination with John et al disclose the at least one predetermined AER characteristic is capable of comprising a dyslexic AER characteristic.

15. **Claim 13**: Finkenzeller et al disclose the AER data processor 1 comprises a control module integral to the frame (Col.4: 65-67).

16. **Claim 14**: Finkenzeller et al disclose the frame 10 includes a disposable portion that includes the electrodes 21, 22.

17. **Claim 15**: Finkenzeller et al disclose the AER data processor 1 necessarily includes digital storage configured to store the AER data.

18. **Claim 16**: Finkenzeller et al disclose the AER data processor 1 is necessarily operably configured to perform a sequence of screening tests, and to store in the digital storage AER data associated with each test.

19. **Claim 17**: Finkenzeller et al disclose the digital storage further includes a predetermined test protocol.

20. **Claim 18**: Finkenzeller et al disclose the AER data processor 1 is further operably configured to generate a user indication of a test condition.

21. **Claim 19**: Finkenzeller et al disclose the frame 10 is operably shaped to connect between the ears across a front portion of a patient's head, best seen in Figure 1-2.

22. In regards to **Claim 20**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose a pair of ear cups attached to each end of the frame. However, Finkenzeller et al teach that the device can be advantageously used for both the left and right ears by rotating the device to position ear cup 30 accordingly (Col.3: 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a pair of ear cups attached to each end of the frame to effectively enable use of both the left and right ears without having to reposition the device.

23. **Claim 21**: Finkenzeller et al disclose the frame 10 comprises an ear cup 30 having a resilient portion inwardly affixed thereto, best seen in Figure 1-2.

24. **Claim 22**: Finkenzeller et al disclose the frame 10 further comprises an ear cup 30 having an electrode 21 registered caudad to the sylvan fissure of a subject, best seen in Figure 1-2.

25. **Claims 23-25 and 27-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al (US Pat No. 5954667) in view of John et al (US Pub No. 20010049480), further in view of John (US Pub No. 20050018858), and even further in view of Clauson et al (US Pat No. 5423327).

26. In regards to **Claims 23 and 28**, Finkenzeller et al disclose a method of performing auditory evoked response (AER) testing, comprising: positioning a device, best seen in Figure 1-2 on the head of a subject, the device positioning a sound producer 30, a reference electrode 22 and a signal electrode 21; generating an auditory stimulus with the sound producer; and recording AER data across the reference and signal electrodes with signal generator/evaluation unit 1, wherein the act of recording AER data comprises receiving electrode voltage data as sensed by the reference electrode and signal electrode (Col.3: 59-65).

27. However, Finkenzeller et al do not disclose a data analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a data analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one

predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a data analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic after connecting the device to the data analyzer, as taught by John et al, to effectively determine the presence of a neurological condition.

28. However, Finkenzeller et al in combination with John et al (2001) do not disclose detecting whether the sensed electrode voltage exceeds a threshold, wherein the act of generating the auditory stimulus further comprises imposing a sampling delay in pursuit of a resting brain state in response to determining that the sensed electrode voltage exceeds a threshold. John et al (2005) teach that a sampling time delay is effective when sampling the AER signal to prevent undue noise or artifacts in the signal (¶0076). Clauson et al teach that detecting whether a signal exceeds a threshold, i.e. a pre-stimulus delay is shorter than the duration of an apnea condition, prior to application of a stimulus, to effectively prevent false readings such as from false positives or artifacts by employing a time delay to return the oxygen saturation level in the blood to normal (Col.3: 58-Col.4: 11). Clauson et al thus teach that it is critical to use a time delay to enable the measured levels to begin at normal before application of the stimulus. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al in combination with John et al (2001) to include detecting whether the sensed electrode voltage exceeds a threshold, wherein the act of generating the auditory stimulus further comprises imposing a sampling delay in pursuit of a resting brain

state in response to determining that the sensed electrode voltage exceeds a threshold, as taught by both John et al (2005) and Clauson et al above, to effectively ensure that the sensed electrode voltage reading is accurate by imposing a sampling delay when the artifact level exceeds a threshold.

29. **Claim 24**: Finkenzeller et al in combination with John et al disclose recording the AER data further comprises necessarily storing the AER data on the device; transmitting the stored AER data to the data analyzer.

30. **Claim 25**: Finkenzeller et al disclose positioning the device on the head of the subject further comprising positioning the subject face up and positioning the device across a forward portion of the subject's head, best seen in Figure 1-2.

31. **Claim 27**: Finkenzeller et al disclose necessarily detecting a resting brain wave and initiating the auditory stimulus at a predetermined slope of the resting brain wave.

32. **Claims 4-6, 8-10, and 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001); or Finkenzeller et al in view of John et al (2001), John et al (2005), and Clauson et al; further in view of Lencioni, Jr (US Pat No. 4219028).

33. In regard to **Claims 4-6 and 30-32**, Finkenzeller et al in combination with John et al (2001), or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose the use of a multiplexing

channel. Lencioni, Jr teaches that a multiplexing channel 18, 20 is effectively used to assign the electrodes of a device to enable proper sampling of the desired electrode in turn (Col.1: 21-22; Col.5: 21-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John et al (2001), or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, to include a multiplexing channel as taught by Lencioni, Jr to effectively enable the AER data processor to selectively sample from the first and second signal electrodes, wherein it is obvious that the electrodes can be sampled at any desired frequency such as sampling the first signal electrode at a low frequency sampling rate and sampling the second signal electrode at a high frequency.

34. In regard to **Claims 8-10**, Finkenzeller et al in combination with John et al (2001), or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose associating a test subject identification with the AER signal. Lencioni, Jr teaches that a test subject identification is associated with a sampled electrode signal to effectively enable distinction of the test results for each individual test subject (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al as modified by John et al (2001), or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, to have a test subject identification associated with the AER signal as taught by Lencioni, Jr, wherein it is well known to a skilled artisan that a test subject identification device may comprises known means such as a barcode scanner or a radio

frequency identification scanner, to effectively enable distinction of the AER signal for different test subjects.

35. **Claims 12 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001); or Finkenzeller et al in view of John et al (2001), John et al (2005), and Clauson et al, further in view of Zoth et al (US Pat No. 6786873).

36. In regards to **Claim 12**, Finkenzeller et al in combination with John et al (2001), or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose the diagnostic analyzer is coupled to the frame via a communication link. Zoth et al teach the advantages of a communication link to remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the diagnostic analyzer coupled to the frame of Finkenzeller et al as modified by John et al (2001), or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, via a communication link as taught by Zoth et al as an effective means to transfer data between the two.

37. In regards to **Claim 29**, Finkenzeller et al in combination with John et al (2001), or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose accessing a remotely stored auditory testing protocol into the device. Zoth et al teach the advantages of a communication link to

remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John et al (2001), or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, access remotely stored data such as an auditory testing protocol as taught by Zoth et al to effectively enable access of necessary data into the device for testing.

38. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001), further in view of John et al (2005).

39. Finkenzeller et al disclose a method of performing auditory evoked response (AER), comprising: positioning a device, best seen in Figure 1-2 on the head of a subject, the device positioning a sound producer 30, a reference electrode 22 and a signal electrode 21; generating an auditory stimulus; and recording AER data across the reference and signal electrodes with signal generator/evaluation unit 1(Col.3: 59-65).

40. However, Finkenzeller et al do not disclose a data analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a data analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to include a data analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic after connecting the device to the data analyzer, as taught by John et al, to effectively determine the presence of a neurological condition.

41. However, Finkenzeller et al in combination with John et al (2001) do not disclose monitoring the AER data for the presence of an artifact and in response to determining the AER data to contain an artifact, imposing a sampling delay and repeating an epoch of auditory stimulus and sampling AER data. John et al (2005) teach that a sampling time delay is effective when sampling the AER signal to prevent undue noise or artifacts in the signal (¶0076). One of ordinary skill in the art would understand that this would include measuring the AER data for the presence of an artifact, and that since the artifact is undesired, if it is detected, a sampling delay should be imposed since it is known that this sampling delay would avoid the presence of the artifacts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al as modified by John et al (2001) such that the AER data is monitored for the presence of an artifact and in response to determining the AER data to contain an artifact, imposing a sampling delay and then repeating an epoch of auditory stimulus and sampling AER data as taught and suggested by John et al (2001), to effectively lessen the effects of noise or artifacts into the epochs of sampled AER data.

Response to Arguments

42. Applicant's arguments with respect to the claims 23-25 and 27-33 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed with respect

to claims 1-22 have been fully considered but they are not persuasive. Applicant contends that Finkenzeller et al do not teach the reference and signal active electrodes each co-located with an amplifier. However, it is noted that since applicant's specification and drawings do not provide any support for the particular configuration of said electrodes co-located and thus integral with said amplifiers, the apparent lack of criticality towards the feature would lead one of ordinary skill in the art to deduce that it would be obvious to have one amplifier for each electrode which would perform the same function as having one amplifier 40 amplify the signals of both the reference and active electrodes 22, 21 as already taught by Finkenzeller et al. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the amplifier as an integral part of the reference active electrode or the signal active electrode, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893), to advantageously produce a more integral device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736